



August 13, 2021

Tyber Medical LLC
Mark F. Schenk
Vice President of Regulatory & Quality
83 South Commerce Way
Suite 310
Bethlehem, Pennsylvania 18017

Re: K203817

Trade/Device Name: Tyber Medical Anatomical Plating System

Regulation Number: 21 CFR 888.3030

Regulation Name: Single/Multiple Component Metallic Bone Fixation Appliances And Accessories

Regulatory Class: Class II

Product Code: HRS, HWC

Dated: July 13, 2021

Received: July 14, 2021

Dear Mark F. Schenk:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm> identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see <https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products>); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems>.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (<https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance>) and CDRH Learn (<https://www.fda.gov/training-and-continuing-education/cdrh-learn>). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (<https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice>) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Shumaya Ali, M.P.H.
Assistant Director
DHT6C: Division of Restorative, Repair
and Trauma Devices
OHT6: Office of Orthopedic Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)

K203817

Device Name

Tyber Medical Anatomical Plating System

Indications for Use (Describe)

The intended use of the Tyber Medical Anatomical Plating System is to draw two or more aligned bone fragments together to facilitate healing and is composed of the following bone plate categories:

Mini-frag/Small Bone System

The Tyber Medical Mini-Frag/Small Bone System is intended for fixation of fractures, osteotomies, nonunions, replantations, and fusions of small bones and small bone fragments including, but are not limited to, the hand, wrist, foot and ankle.

The Tyber Medical Mini-frag/Small Bone System is not for Spinal Use.

Foot System

The Tyber Medical Foot System is Indicated for Use in fixation of small bones and small bone fragments in the foot (Phalanges and Metatarsals), and medium/ large bones and medium/large bone multi-fragments in the foot (Cuneiform, Cuboid, Navicular, Talus and Calcaneus) for stabilization of fractures, joint fusions, osteotomies, nonunions, malunions, reconstruction of small, medium and large bones, revision surgeries and replantations in an adult patient.

The Tyber Medical Foot System is not for Spinal Use.

Long Bone Fracture System

The Tyber Medical Long Bone Fracture System is intended for osteotomies and non-unions, fixation of fractures of the clavicle, scapula, olecranon, humerus, radius, ulna, fibula.

The Tyber Medical Long Bone Fracture System is not for Spinal Use.

Type of Use (Select one or both, as applicable)

Prescription Use (Part 21 CFR 801 Subpart D)

Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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Indications for Use

510(k) Number (if known)

K203817

Device Name

Tyber Medical Anatomical Plating System

Indications for Use (Describe)

(Continued)

Ankle Fracture/Fusion System

The Tyber Medical Ankle Fracture/Fusion System is Indicated for Use in:

- 1). Fixation of fractures of the distal tibia included, but not limited to, ankle fractures, perarticular fractures, corrective osteotomies, non-unions, intra- and extra- articular and distal tibia fractures with a shaft extension, and malleolar fractures;
- 2). In intra- and extra articular fractures, osteotomies, medial malleolar fractures and non-unions of the metaphyseal and diaphyseal region of the distal fibula, and calcaneus;
- 3). In distal tibia/fibula long bones which include the metaphyseal and diaphyseal regions of the tibia and fibula in the ankle.

The Tyber Medical Ankle Fracture/Fusion Plating System is not for Spinal Use.

Type of Use (Select one or both, as applicable)

Prescription Use (Part 21 CFR 801 Subpart D)

Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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Traditional 510(k) Summary
as required by section 807.92(c).

**Tyber Medical
Anatomical Plating System**

K203817

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|--------------------------------|---|
| Submitted | 8/13/21 |
| Submitter: | Tyber Medical LLC 83 South Commerce Way, Suite 310 Bethlehem, PA 18017 |
| Contact Person | Mark Schenk V.P. Regulatory Phone: 610-849-0645 Email: mschenk@tybermed.com |
| Trade Name | Tyber Medical Anatomical Plating System |
| Common Name | Plate, Fixation, Bone; Screw, Fixation, Bone |
| Device Class | Class II |
| Classification Name and Number | Single/multiple component metallic bone fixation appliances and accessories (21 CFR 888.3030) - Primary Smooth or threaded metallic bone fixation fastener (21 CFR 888.3040) |
| Classification Panel: | Orthopedic |
| Product Code | HRS, HWC |

Predicate Devices

| System | Primary Predicate | Additional Predicates |
|------------------------------|---|--|
| Mini-frag/Small Bone | Tyber Medical Anatomical Plating System (K193222) | ORTHOLOC® 3Di Small Bones Plating System (K163039) |
| Foot System | Tyber Medical Anatomical Plating System (K193222) | ORTHOLOC® 3Di Foot Plating Reconstruction System (K152974) |
| Long Bone Fracture System | Tyber Medical Anatomical Plating System (K193222) | AxSOS 3 Ti; Stryker Plating System (K162439) |
| Ankle Fracture/Fusion System | Tyber Medical Anatomical Plating System (K193222) | Baby Gorilla/Gorilla Plating System (190365) |

| System | Primary Predicate | Reference Predicates |
|--------|---|---|
| Screws | Tyber Medical Anatomical Plating System (K193222) | Tyber Medical Trauma Screw System (K133842) |

Device Description

The Tyber Medical Anatomical Plating System consists of the following categories:

1. Mini-frag/Small Bone System
2. Foot System
3. Long Bone Fracture System
4. Ankle Fracture/Fusion System

A brief and concise description of each system is as follows:

Mini-frag/Small Bone System

The Tyber Medical Mini-frag/Small Bone System offers a variety of plates for fixation of bone fragments. The system incorporates a series of standard and locking compression plates and screws of varying lengths, thicknesses, and configurations including 1). Straight Fracture Plates, 2). T-shape Fracture Plates, 3). Y-shape Fracture Plates, 4). L-shape Fracture Plates, 5). Cloverleaf plates, 6). Straight Fusion Plates, 7). Oblique Fracture Plates, 8). Oblique Fracture Compression Plates, 9). Double Y-Shape Plates, 10). Zig-Zag Plates, 11). Partial Zig-Zag Plates, 12). Mesh Plates

The System will incorporate both Cortical Locking Screws and standard Cortical Non-Locking Screws in 2.0mm, 2.5mm, 2.8mm, 3.0mm and 3.5mm sizes in various lengths. All plates are composed of Ti-6Al-4V ELI (ASTM F136) or Stainless Steel (316L) with an Anodized Type II surface treatment. All screws are composed of Ti-6Al-4V ELI (ASTM F136) or Stainless Steel (316L) with color anodized for sizing.

A full set of Ancillary instrumentation is available with the system. The Tyber Medical Mini-frag/Small Bone System is offered both sterile and non-sterile for single-use.

Foot System

The Tyber Medical Foot System consists of a variety of plates with shapes and sizes designed for internal fixation of small bone fragments of the foot. The implants are designed to provide highly anatomic and versatile options for an array of fusions and stabilizations of small bones in the feet. The plates are available in various lengths, with straight, right and left configurations. Plate types consist of 1). TMT-I Fusion Plates, 2). Open Wedge Plates, 3). Navicular Plates, 4). Cuboid Plates, 5). Lateral Talar Neck Plates, 6). Akin Plates, 7). 5th Metatarsal Jones Fracture Plates, 8). 5th Metatarsal Fracture Compression Plates, 9). 5th Metatarsal Avulsion Fracture Plates, 10). Medial Talar Neck Plates, 11). Distal Medial Column Plates, 12). ORIF Calcaneal Plates, 13). ORIF Standard Calcaneal Plates, 14). Rectangular Plates, 15). X-Plates, 16). Cotton Plates, 17). Dwyer Plates, 18). MTP Fusion Plates, 19). MTP Fusion Revision Plates, 20). Stepped Lapidus Plates, 21). Plantar TMT Plates, 22). Medial Column Plates, 23). Evans Osteotomy Plates, 24). TMT-I Medial Fusion Plates, 25). Sinus Tarsi Plates, 26). 1st 2nd Ray Lisfranc Joint Plates, 27). 2nd and 3rd Ray Lisfranc Joint Plates, 28). Perimeter Calcaneus Plates, 29). Navicular Cuneiform Plates, 30). Talonavicular Plates.

The system will incorporate both Cortical locking and standard Cortical Non-locking screws. All plates are composed of Ti-6Al-4V ELI (ASTM F136) or Stainless Steel (316L) with an Anodized Type II surface treatment. All screws are composed of Ti-6Al-4V ELI (ASTM F136) or Stainless Steel (316L) with color anodized for sizing.

A full set of Ancillary Instrumentation is available with the system. The Tyber Medical Foot System is offered both sterile and non-sterile for single-use.

Long Bone Fracture System

The Tyber Medical Long Bone Fracture System consists of a straight low contact locking plate and a 1/3 locking tubular plate. The system will incorporate both Cortical locking and standard Cortical Non-locking screws. All plates are composed of Ti-6Al-4V ELI (ASTM F136) or Stainless Steel (316L) with an Anodized Type II surface treatment. All screws are composed of Ti-6Al-4V ELI (ASTM F136) or Stainless Steel (316L) with color anodized for sizing.

A full set of Ancillary Instrumentation is available with the system. The Tyber Medical Long Bone Fracture System is offered both sterile and non-sterile for single-use.

Ankle Fracture/Fusion System

The Tyber Medical Ankle Fracture/Fusion System is designed to address a variety of indications in ankle reconstruction mid-shaft and distal tibia/fibula fixation surgery. The system is composed of various locking plate types which include 1). Posterior Tibia Plate, 2). Fibula Plate, 3). Medial Tibia Plate, 5). Anterolateral Tibia Plate, 6). Medial Malleolus Hook Plate, 7). Medial Malleolus Plate, 8). Fibula Hook Plate, Straight, 9). Fibula Hook Plate, Anatomic, 10). Anterior Tibia Plate, 11). Anterior TT Plate, 12). Anterolateral TT Plate, 13). Lateral TT Plate, 14). Lateral TTC Plate, 15). Posterior TTC Plate, 16). Posterolateral Tibia Plate, 17). Posteromedial Tibia Plate, 18). Trimalleolar Plate, 19). Posterior Fibular Plate.

The System will incorporate both Cortical Locking Screws and standard Cortical Non-locking Screws in various lengths. All plates are composed of Ti-6Al-4V ELI (ASTM F136) or Stainless Steel (316L) with an Anodized Type II surface treatment. All screws are composed of Ti-6Al-4V ELI (ASTM F136) or Stainless Steel (316L) with color anodized for sizing.

A full set of Ancillary Instrumentation is available with the system. The Tyber Medical Ankle Fracture/Fusion System is offered both sterile and non-sterile for single-use.

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| Intended Use | The intended use of the Tyber Medical Anatomical Plating System is to draw two or more aligned bone fragments together to facilitate healing. |
| Indications for Use | <p>Mini-frag/Small Bone System</p> <p>The Tyber Medical Mini-Frag/Small Bone System is intended for fixation of fractures, osteotomies, nonunions, replantations, and fusions of small bones and small bone fragments including, but are not limited to, the hand, wrist, foot and ankle.</p> |

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| | <p>The Tyber Medical Mini-frag/Small Bone System is not for Spinal Use.</p> <p>Foot System The Tyber Medical Foot System is Indicated for Use in fixation of small bones and small bone fragments in the foot (Phalanges and Metatarsals), and medium/ large bones and medium/large bone multi-fragments in the foot (Cuneiform, Cuboid, Navicular, Talus and Calcaneus) for stabilization of fractures, joint fusions, osteotomies, nonunions, malunions, reconstruction of small, medium and large bones, revision surgeries and replantations in an adult patient. The Tyber Medical Foot System is not for Spinal Use.</p> <p>Long Bone Fracture System The Tyber Medical Long Bone Fracture System is intended for osteotomies and non-unions, fixation of fractures of the clavicle, scapula, olecranon, humerus, radius, ulna, fibula. The Tyber Medical Long Bone Fracture System is not for Spinal Use.</p> <p>Ankle Fracture/Fusion System The Tyber Medical Ankle Fracture/Fusion System is Indicated for Use in: 1). Fixation of fractures of the distal tibia included, but not limited to, ankle fractures, perarticular fractures, corrective osteotomies, non-unions, intra- and extra- articular and distal tibia fractures with a shaft extension, and malleolar fractures; 2). In intra- and extra articular fractures, osteotomies, medial malleolar fractures and non-unions of the metaphyseal and diaphyseal region of the distal fibula, and calcaneus; 3). In distal tibia/fibula long bones which include the metaphyseal and diaphyseal regions of the tibia and fibula in the ankle. The Tyber Medical Ankle Fracture/Fusion Plating System is not for Spinal Use.</p> |
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| Statement of Technological Comparison and Fundamental Scientific Technology | The Tyber Medical Anatomical Plating System is similar in design, material, technological characteristics and indications when compared to the predicate devices. |
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| Nonclinical Testing Summary | Testing according to ASTM F382-17, "Standard Specification and Test Method for Metallic Bone Plates," has been completed on the identified worst-case plates to characterize the mechanical performance and fatigue endurance of the |
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| | <p>Tyber Medical Anatomical Plating System. Results of the testing demonstrate that the system is substantially equivalent to legally marketed predicates.</p> <p>The proposed bone screws are comparable to the previously cleared Tyber Medical Trauma Screws. These screws have identical major and minor thread diameters and thread profiles per size. No new worst case has been created.</p> |
| Clinical Test Summary | n/a |

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| Conclusion | The Tyber Medical Anatomical Plating System is similar in design, material, technological characteristics, and indications when compared to the predicate devices. |
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